Ethics Handbook

for

Teaching and Research

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Version History

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Committee Sign Off

Version	Committee Name	Date of Sign Off
2	University Ethics Committee	13 Nov 2013
2.1	University Ethics Committee	20 Jan 2016
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3.1	University Ethics Committee	25 Jan 2017
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3.3	University Ethics Committee	28 Nov 2018

Ethics Handbook for Teaching and Research

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1. Introduction

The University exists to advance and disseminate knowledge and learning while maintaining proper ethical standards. Therefore, in January 1973, the Senate set up a University Ethics Committee (UEC) with the remit to draw up a set of Principles and Procedures for teaching and research within the University which involved considerations of an ethical nature.

In July 2003, the Senate approved a revision to the title, constitution and the membership provision of the UEC and to the terms of reference. Further revisions in 2008 and 2010 increased the membership and also ensured that all relevant disciplines are covered thoroughly by staff expertise.

The Ethical Principles and Procedures and Terms of Reference outlined in this document are those approved by the Senate on 2 May 1978, on 28 June 1988 and subsequently. In November 2013, the name of this document changed from 'Ethical Guidelines in Teaching and Research' to 'Ethical Principles and Procedures for Teaching and Research' and in June 2016, to 'Ethics Handbook for Teaching and Research'.

1.1. Purpose

The purpose of this handbook is to support all researchers in their consideration of ethical issues arising from academic activity, in accordance with certain general principles and standards approved by the University. Although the decision to undertake an academic activity such as research rests with each individual, such decisions must be taken within the broader ethical framework of the University, and it is the responsibility of the individual to seek guidance on and, if necessary, approval for activities which might be ethically sensitive.

The ethical standards which apply to academic activities (including research, teaching, consultancy and expert services and outreach work) arise from the basic principle that such activities should neither include practices which directly impose a risk of serious harm nor be indirectly dependent upon such practices. Serious harms include, for example, failure to protect the reputation of the University, failure to respect the welfare and interests of the wider community and damage to items of cultural value or the natural environment. Ethical practice also requires that the use of animals in academic work is fully justified and that statutory controls and codes of practice are observed at all times.

All activities undertaken by staff and students as members of the University must comply with the University's ethical standards.

1.2. University Ethics Committee Terms of Reference

i) To consider all issues arising within the University which involve considerations of an ethical nature;

ii) To prepare a set of principles and procedures in relation to ethical issues which may arise from teaching and research activities within the University;

iii) To be available for consultation on such ethical issues by the Senate or any other corporate body, and by individual members of staff or students of the University;

iv) To consider, and in appropriate cases grant a favourable ethical opinion of, specific representations and research protocols submitted to it by members of staff and students of the University, or representatives of certain external bodies working in collaboration with members of the University;

v) To report on the exercise of the UEC's functions, and make recommendations to the Senate as appropriate on key matters of policy and strategy related to ethics.

vi) To ensure research is carried out in accordance with the University's research values as outlined below.

vii) The current constitution of the UEC is shown in Appendix I.

1.3. Research values

The University Ethics Committee recognises and endorses the 'Concordat to support research integrity' as published by Universities UK. The University Ethics Committee is committed to maintaining the highest standards of rigour and integrity in all aspects of research. The core elements of this are:

Honesty - 'in all aspects of research, including in the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of other researchers; and in conveying valid interpretations and making justifiable claims based on research findings'

Rigour - 'in line with prevailing disciplinary norms and standards: in performing research and using appropriate methods; in adhering to an agreed protocol where appropriate; in drawing interpretations and conclusions from the research; and in communicating the results'.

Transparency and open communication - 'in declaring conflicts of interest; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes sharing negative results as appropriate; and in presenting the work to other researchers and to the general public.' and

Care and respect - 'for all participants in and subjects of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the stewardship of research and scholarship for future generations'.

1.4. National and International guidance on ethics

All teaching experiments and research carried out in, and by members of, the University of Surrey should conform with the 'Universal Declaration of Human Rights and Covenants on Human Rights' (UN General Assembly, December 1984) and with the University's ethical principles and procedures. Researchers are also required to

observe the ethical principles and procedures advocated by their own appropriate Society or Professional Body.

1.5. Supervisory responsibilities

1.5.1 Responsibility of Deans of Faculty and Heads of Department

Deans of Faculty/Heads of Department are responsible for teaching and research carried out within their own Faculty/Department and under the supervision of their own staff.

1.5.2 Responsibility of research supervisors

It is the responsibility of all supervisors to ensure that any students involved as researchers or in conducting experimentation are aware of the ethical principles and procedures in this handbook.

It is also the role of the supervisor to approve the content of submissions from researchers under their supervision and to check the researcher's documentation, ensuring that any inaccuracies including spelling and grammar are corrected, before signing the application off, prior to submission to the Committee.

1.6. Definitions

The definitions given against the following terms are provided for the purpose of this document only.

Clinical Trials – are statutorily defined by the Medicines and Healthcare Products Regulatory Agency under the Medicines for Human Use (Clinical Trials) Regulations 2004 as:
'any investigation in human subjects, other than a non-interventional trial, intended

(a) to discover or verify the clinical, pharmacological or other pharmacodynamics of one or more medicinal products,
(b) to identify any adverse reactions to one or more such products, or
(c) to study absorption, distribution, metabolism and excretion of one or more such products,

with the object of ascertaining the safety or efficacy of those products'.

Human participants - The World Health Organization Manual (Section XV.2) defines research with human subjects as 'any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge, in which human beings:

a) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment, or
b) become individually identifiable through investigator's collection, preparation, or use of biological material or medical or other records.'

The term 'participant' should also be taken to include any members of the research team or colleagues who volunteer to be subjects of the research.

Principal Investigator – This means the lead Investigator of the research protocol, who may also be known as the Chief Investigator.

Research – The University defines Research as 'the pursuit and advancement of knowledge' in the Code on Good Research Practice.

Researcher – The University defines Researcher as 'all those engaged in academic research and consultancy' in the Code on Good Research Practice.

Sponsor – The Sponsor takes legal responsibility for initiation and management of the research study, provides insurance for the study and is not necessarily the funder. For Clinical Trials, the European Commission Directive 2001/20/EC define the sponsor as: 'An individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial'.

2. When is an Ethical Review Required?

All research requires a form of ethical assessment, however, if research involves data that are not in the public domain, and/or involves using other human participants (e.g. in questionnaires, interventions or interviews), human tissue, or animals, then some form of ethical review of the research would normally be required.

2.1. Ethical review by external bodies

If the study is being led by the University of Surrey you must contact the Research Integrity and Governance Office (RIGO) by email before making an application to any external review body.

2.1.2 NHS ethical review

Review by an NHS Research Ethics Committee (REC) is required for certain research projects, for example, but not limited to, studies that involve NHS patient groups, characterised by a specific disease or disorder, or their carers, adults lacking capacity to consent for themselves, investigational medicinal products/devices and ionising radiation. Please consult the Health Research Authority website for more information.

The UEC recognises a favourable ethical opinion (FEO) from the NHS. If your study requires sponsorship from the University of Surrey under the UK Framework for Health and Social Care Research, please see the RIGO webpages.

2.1.3 MODREC ethical review

The Ministry of Defence Research Ethics Committee (MODREC) ensures that all research involving human participants either undertaken, funded or sponsored by MOD meets nationally and internationally accepted ethical standards.

The UEC recognises a favourable ethical opinion (FEO) or approval from the MODREC.

2.2. Ethical opinion from collaborating organisations

2.2.1 Hospitals and Clinics

Research protocols which involve access to subjects under the day to day care of a hospital or clinic will need to produce evidence that the investigator has the agreement

of the appropriate Ethical Committee governing the hospital(s) or clinic(s) concerned. Similarly, protocols which use hospital or clinical premises, other than those which are available within the University, will normally need to produce such evidence. Additional legal and ethical approvals may need to be obtained (section 3.4.).

2.2.2 Higher Education Institution (HEI)

Research that requires external review by another Higher Education Institution (HEI) may require an ethical review by the UEC, but this will be decided on a case by case basis. Researchers are advised to contact RIGO by email prior to the external ethical review process being initiated.

2.3. Reviewing protocols from associated institutions

The UEC is prepared to consider and grant an ethical opinion to protocols from those of the University's Associated Institutions that do not have Ethics Committees of their own, provided that the protocols arise directly or indirectly from undergraduate or postgraduate programmes which are validated by the University of Surrey. In these circumstances, the Ethics Committee (or representative thereof) reserves the right to inspect the appropriate premises and facilities within the institution.

2.4. Research conducted outside of the UK

The researcher should, where possible, refer to country-specific guidelines for the location where research is being carried out. The International Compilation of Human Research Standards is a listing by the US Department of Health and Human Services of over 1,000 laws, regulations, and guidelines (including ethics committees) on human subjects' protection in over 100 countries and from several international organisations. Details of country-specific requirements and how these are met should be included in protocol submissions to UEC (even if this is to confirm that additional action is not necessary). It is also recommended that researchers confirm they are covered by the University's travel insurance and they should ensure that their visa will allow for research to be conducted . Researchers going abroad should also regularly check the British Foreign Commonwealth Office website for further details and travel advice for the country they are planning to visit.

2.5. Criteria for ethical review by the University Ethics Committee (UEC)

All research involving human participants should be evaluated against the criteria listed below for review by the UEC before recruitment of study participants begins. Researchers at the University can carry out this evaluation using Self-Assessment For Ethics (SAFE): the online self-assessment tool for staff and postgraduate research (PhD and EngD) students (section 3.1.).

Research should be reviewed on a project basis. An FEO is normally given for an individual project rather than a general procedure or research method. An application may cover a complete study in all of its different phases or stages, or submissions may be made for each individual stage or phase separately. The FEO will cover all activities that will be carried out in the specific application.

2.5.1. Full UEC review criteria

Full UEC review is required for projects meeting one or more of the following criteria:

a) Procedures involving more than minimal risk to a participant's health or well-being (e.g. intrusive psychological and physiological procedures, including the risk of administering any substances).

b) Procedures involving the use of surveys, questionnaires and any research, the nature of which might be offensive, distressing or deeply personal for the particular target group, where the participants **will be identifiable to the researchers** e.g. interviews, focus groups. *This may include questions on special category data (sensitive data) e.g. ethnicity, political views, religion, physical or mental health conditions, and sexual life/orientation.*

c) Procedures involving children under the age of 16 or other vulnerable groups, or those who may feel under pressure to take part due to their connection with the researcher. *Please note that you may need DBS clearance for working with anyone under 18 years of age even though those 16 and over are usually considered capable of consenting for themselves.*

d) Research involving prisoners or young offenders. *If the research requires Her Majesty's Prison and Probation Service (HMPPS) approval, please contact the Research Integrity and Governance Office (RIGO) by email before making any application to the HMPPS.*

e) Research protocols which require participants to take part in the study without their knowledge and/or consent at the time *For example, covert observation where adults might reasonably expect that their behaviour would not be observed by third parties. This does not include observational research taking place in public venues, either physical (e.g. a town square, conference, or meeting open to the public), or virtual (e.g. a public chat room).*

f) Research which involves deception other than withholding information about the aims of the research until the debriefing.

g) Research where for any other reason the researcher feels significant ethical concerns may arise, or where an external funding body or sponsor requires full ethical review to be undertaken.

2.5.2. Full UEC review (for any studies involving human tissue)

The collection and storage of human tissue is governed by the Human Tissue Act 2004. Ethical review is required for projects meeting one or more of the following criteria:

a) Research involving the new collection or donation of human tissue from a living person or the recently deceased as defined by the Human Tissue Authority (HTA).

b) Research involving previously collected human tissue must not commence until after the researchers have contacted the Research Integrity and Governance Office (RIGO) by email for advice on any necessary approvals. The research may still need review by the University Ethics Committee.

Separate approval is required from the University HTA Governance Committee before a full UEC review can be completed.

2.5.3. Proportionate UEC review criteria

Proportionate UEC review usually benefits from a shorter turnaround time and is available for projects that meet one or more of the following criteria and none of the criteria for full review:

a) Studies involving the use of surveys, questionnaires and any research, the nature of which might be offensive, distressing or deeply personal for the particular target group, where the participants **will not be identifiable to the researchers** e.g. online surveys, anonymous questionnaires. *This may include questions on special category data (sensitive data) e.g. ethnicity, political views, religion, physical or mental health conditions, sexual life/orientation. The researcher must be sure that no identifiable data is collected with the research data.*

b) Research involving the accessing of records and/or the collection of personal identifiable data, concerning identifiable individuals as defined by data protection legislation. *Personal data means data which relates to a living individual who can be identified. This includes special category data (sensitive data) as well as academic and career information and some protected characteristics according to the Equality Act 2010, e.g. disability, marriage and pregnancy.*

c) Research involving the linking or sharing of personal data, *special category data (sensitive data)* or confidential information **beyond the initial consent given** (including linked data gathered outside of the UK). *For example, where the research topic or data-gathering involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.*

d) Research involving the collection or access of audio, video recordings, photographs or quotations within which participants may be identifiable and with the intention to disseminate them beyond the research team. *This includes publicly available information for example on social media and participants recruited or identified through the internet, when the understanding of privacy in these settings is contentious, where sensitive issues are discussed or where visual images are used.*

e) Protocols which include offering incentives which may unduly influence participants' decision to participate. *This includes where the compensation amounts to an hourly rate more than the living wage or more than £100 in total, or equivalent in an international context. The following are excluded from this*

criterion: reimbursement for out of pocket expenses, provision of refreshments or entry into a low-value prize draw.

f) Studies involving activities where the safety/wellbeing of the researcher may be in question. *It is expected that in all cases researchers adhere to the relevant University of Surrey Health & Safety policies and other local procedures e.g. for lone working.*

g) Studies where behavioural/physiological intervention could possibly lead to discovery of ill health or concerns about wellbeing in a participant incidentally, even if the intervention in itself causes no more than minimal stress is to the research participant. *This includes cases where **there is a significant likelihood that** information may arise in the course of fieldwork that is a cause for concern, such as disclosures from participants or behaviours or incidents observed that raise significant concerns or test results that may indicate health concerns.*

h) Studies involving the investigation of existing working or professional practices among participants, identifiable to the researcher at their own place of work. *This may be at the University of Surrey or another organisation where either the researcher, the supervisor or the co-investigator works.*

i) Research protocols to be carried out by persons unconnected with the University, but wishing to use staff and/or students as participants.

j) Projects reviewed by another higher education institution that require review according to section 2.2.2.

Note: Submissions for proportionate review may be referred for full review if the initial reviewer identifies significant ethical issues.

3. Applying for Ethical Review by the University

Faculty Ethics Committees (FECs) are responsible for reviewing protocols submitted by **Undergraduate** and **Postgraduate (Taught)** students in their Faculty, including those on practitioner Doctorates (e.g. PsychD), where the research project is a relatively minor component. Exceptions to this are practitioner Doctorates with a more substantial research component (e.g. EngD), where applications should be submitted to the UEC.

The University Ethics Committee (UEC) is responsible for reviewing protocols submitted by **Postgraduate (Research)** students, **staff** and **all other groups**.

3.1. Online Self-Assessment For Ethics (SAFE)

An online Self-assessment tool to enable researchers to check their research against the criteria listed in 2.5 has been developed, named the Self-Assessment For Ethics (SAFE). All staff and doctoral researchers undertaking research are expected to use the new online self-assessment form (SAFE) to determine if their research qualifies for ethical review and then whether to apply for proportionate or full review by the UEC. This allows for reviews to be conducted in proportion to the complexity and risks of each project.

This self-assessment aims to raise awareness of ethical issues for all researchers and give those conducting low-risk studies confidence that they have made a well-informed judgement that ethical review by UEC is not needed.

The self-assessment form is submitted online following the instructions on the RIGO webpages before recruitment commences.

Self-assessment does not in itself constitute support for a favourable ethical opinion: a favourable ethical opinion may only be issued on the basis of a full or proportionate ethical review by the relevant ethics committee. All research conducted under the auspices of the University, is required to abide by the provisions of this document and the Code on Good Research Practice as well as any other relevant University policies and external regulations.

Where changes are made to the protocol the self-assessment should be repeated and the project submitted for review as appropriate.

3.2. Information on the submission process to the UEC

Where a need for ethical review by the University's Ethics Committee is indicated by self-assessment, you should complete the Ethics Application Form and the necessary accompanying documents listed on its checklist. This form and further guidance are available, from the RIGO webpages The UEC will endeavour to deal with applications expeditiously, but those submitting protocols are advised to allow 28 days from the notification email from the RIGO that their application has been sent for review.

For governance purposes, all study protocols and associated documentation such as participant information sheets and consent forms should have version numbers and dates. Documentation should be proof-read before submitting it for the consideration of the UEC. If spelling errors are identified in the initial checks, all documentation may be returned to the researcher. Failing to proof-read study documentation can cause significant delays in the UEC reviewing process.

Further information, guidance and templates related to any of the University ethics processes can be found on the RIGO webpages. If in doubt, please contact the RIGO by email.

3.3. Insurance and contracts required

It is an insurance requirement that the University needs to know what arrangements will be made for insurance and/or indemnity to meet the University's potential legal liability for harm to participants arising from the management, design and/or conduct of the research. The correct insurance proforma must be submitted with any application for ethics review. Also, legal agreements will need to be in place if a study uses the services of or involves a third party (i.e. NHS, tissue samples from NHS Trusts, expert consultants, other Universities etc.), to establish that that all third parties hold appropriate legal liability insurance. Detailed guidance on insurance and legal contracts/agreements for research can be obtained from the internal University Insurance webpages.

3.4. Additional approvals and considerations required

3.4.1. Health and Safety approval

All researchers should make sure that all local Health and Safety approvals are in place. More detailed guidance is available via the University's Health and Safety pages.

3.4.2. Additional ethical or legal approval

It is the researcher's responsibility to ensure they obtain any additional ethical, legal or other approvals. These approvals can be from institutions hosting the research and/or approval from local organisations or gatekeepers (see Section 2.2). The need for additional permissions should also be considered if the research is being conducted outside the UK (see section 2.4).

3.5. Pilot studies

Any pilot studies that require participants to take part in a procedure that would qualify a study for review according to criteria specified in Section 2.5 should be submitted to the relevant ethics committee for the relevant review.

3.6. Translation of documents

The UEC considers translated documents on a case-by-case basis where no official translation can be provided. On the whole, the UEC would accept the researcher's own signed translation provided that it was accompanied by the original document, but this would be subject to consideration. Where applicable, the supervisor/Principal Investigator should also sign to agree the accuracy of the translation and this would be acceptable. The UEC might also request further information and evidence from the researcher if presented with a document in a foreign language.

3.7. Amendments and the expiry of a favourable ethical opinion

The UEC should be notified of any changes to the protocol, any adverse reactions, or if the study is to be repeated using a different group of research participants or lead researcher/s.

If changes are required by external bodies, these changes should be referred back to the UEC as an amendment. Amendments should not be implemented before the appropriate confirmation of acknowledgement from the relevant ethics committee or a new FEO has been obtained.

A further submission to the UEC will be required in the event that the study is not completed within five years of the date of the FEO. Also, the UEC should be advised when your research project has not proceeded according to the timescale specified in the original application, for example if it has been terminated early or if you are still collecting data after the proposed end date of the study.

If your study has not started within a year of the FEO, you must update the UEC giving the reasons why.

4. University Ethics Committee Procedure

Although the University Ethics Committee (UEC) meets three times a year, research protocols requiring ethical review by the UEC are dealt with by correspondence on a continuous basis. RIGO provides the secretariat support for UEC processes. Protocols are given a **favourable ethical opinion** (i.e. the terminology 'approval' is not used) on the unanimous decision of a subset of the UEC members and not on a majority decision.

Special meetings of the UEC can be convened to resolve any issue in the event that any member expresses a major reservation about a particular protocol and that issue is not resolved by the investigator.

4.1. Auditing of protocols

A sample of all protocols received by the UEC as well as those submitted as part of self-assessment are audited at a later date. The University uses the audit process to identify any gaps in processes or sharing of information across the University. Where any concerns are raised by the auditing staff, these are initially discussed informally with the researcher to provide advice on how to proceed, although the potential exists for such cases to be referred for investigation under the provisions of research misconduct policies. Researchers are contacted by the RIGO in the event of their protocol being selected for audit.

4.2. Confidentiality and conflict of interest

In order to encourage and foster open and candid discussion at its meetings, members of the UEC shall keep confidential any and all information relating to discussions at its meetings, unless compelled by legal process to disclose such information, or as otherwise agreed by the UEC (Chatham House Rule shall apply).

It is expected that members of University of Surrey Ethics Committees will treat material submitted for review as confidential and not make use of it to gain an unfair academic advantage. Any type of peer review is in itself a learning process, however, members must never derive academic or commercial competitive advantage from information they acquire in the process of reviewing applications.

It is vital that all reviewers are seen to be impartial at all stages of the review process. Reviewers are briefed at induction on the requirements for confidentiality and the nature of conflicts of interest. They should not take part in the review of any proposal where a conflict of interest may be experienced or perceived and are required to declare any conflict of interest to RIGO if they should inadvertently be invited to take part in a review where such a conflict of interest exists.

These points are summarised in the University of Surrey Ethics Committees 'Conflict of Interest and Confidentiality Statement' in Appendix II.

4.3. University Ethics Committee: Appeals procedure

Following a decision of the University Ethics Committee not to grant a favourable ethical opinion, the Principal Investigator will have the right to appeal this decision according to the rules described below. The appeals procedure should **only** be

implemented when the University Ethics Committee and the Principal Investigator fail to reach agreement following comprehensive dialogue.

If the University Ethics Committee finds it is unable to grant a favourable ethical opinion, it will inform the Principal Investigator, in writing, of its decision and shall state clearly the reason(s) behind its decision.

The Principal Investigator has 14 days from the date of the written notification from the University Ethics Committee to petition the Vice Chancellor for an appeal. The Principal Investigator must state clearly the grounds upon which the request is based. Appeals should be based on one or both of the following:

- a failure on the part of the University Ethics Committee to follow its own procedures;
- a perverse decision by the University Ethics Committee*.

(* a perverse decision is one which no other University Ethics Committee, which has been provided with the same level of information from the applicant, would reach)

A direct challenge to the academic judgement of the University Ethics Committee will be considered insufficient for the granting of an appeal.

On receipt of a request for an appeal against a decision of the University Ethics Committee, the Vice Chancellor will determine whether or not to grant an appeal hearing. In so doing, the Vice Chancellor may seek advice and may, as necessary, interview either, or both of, the Chair of the University Ethics Committee and the Principal Investigator. If the Vice Chancellor determines not to grant an appeal hearing, the decision of the University Ethics Committee will stand.

Should the Vice Chancellor permit an appeal hearing, they will direct the Academic Registrar to establish an appeal panel with the following membership:

- a Chair who will be a Provost,
- two senior members of academic staff from Faculties other than that of the Principal Investigator.

In hearing the appeal, the panel will interview separately the Chair of the University Ethics Committee and the Principal Investigator. The Principal Investigator may be accompanied at the hearing, where appropriate, by another person connected to the proposed research project. The panel may also interview other persons as it deems necessary. The panel will inform the Academic Registrar of its decision and the reasons behind it; this will then be communicated in writing to both the Chair of the University Ethics Committee and the Principal Investigator within seven days. The decision of the appeal panel will be final.

5. Involvement of Students in Research and Teaching Activities

5.1. Teaching activities

Teaching experiments and research studies involving blood sampling or the handling of blood and other human specimens must be carried out in accordance with the Human Tissue Act, 2004 and the University's Code on Good Research Practice.

The UEC considers that it is ethically acceptable to request an undergraduate or postgraduate student to participate in physiological experiments (e.g. swallowing a naso-gastric tube or using an exercise bicycle), or in experiments in the behavioural sciences as a normal part of his/her programme on the understanding:

a) that the supervisor ensures that all such studies conform with the University's Ethics Handbook for Teaching and Research;

b) that the student/participant has the right to decline a particular procedure on religious, physiological grounds etc.;

c) that the student/participant must be assured that, by declining to participate in a particular procedure, his/her marks will NOT be adversely affected;

d) that undue academic pressure or financial inducement shall not be brought to bear on the student;

e) that the policy and procedures listed below in section 5.4 be observed relating to students undertaking tests as a routine part of a programme of teaching or research, from which unexpected results with possible health implications for the participants might arise;

f) that it is the responsibility of the members of staff responsible for those conducting the experiment, to take reasonable steps to ascertain that the student is in good health and knows of no reason why he/she should not participate.

If the results of the above mentioned activities are to be used for research purposes then the project should be evaluated against the criteria for ethical review (section 2.5). In addition, if students' data (demographics, personal data, work contributing to their degree) are to be used in a different way than described in the University's Intellectual Property policy or the research otherwise goes beyond the terms of consent implied by the student's participation in the teaching activity, then additional consent to take part in the research should be sought.

5.2. The use of animal tissues in teaching

Some fundamental principles in biology and physiology may be taught using body tissues. If this is the case the *in vitro* studies are carried out using tissues isolated from animals (which would be derived from animals used for research purposes) following euthanasia using humane methods approved under the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012. Wherever possible, animal use is limited by replacement with appropriate educational alternatives.

The understanding of animal metabolism and physiology is not complete without some studies on animal tissues. Thus students in the Biological Sciences should expect to be involved in such studies.

Any student may decide that they do not wish to participate in any particular exercise involving animal tissue, and this is acceptable provided that they inform the member of staff responsible for that practical in advance. Normally the student will then receive an alternative piece of coursework.

5.3. The teaching of veterinary clinical skills in veterinary education

The teaching of skills to veterinary students is controlled by the Veterinary Surgeons (Practice by Students) (Amendment) Regulation 1993 made under the Veterinary Surgeons Act 1966. The Royal College of Veterinary Surgeons (RCVS) is responsible for monitoring veterinary education and professional training.

5.4. Policy relating to students undertaking tests as a routine part of a programme of teaching or research, from which unexpected results with possible health implications might arise.

If the results of such tests are to be used for research purposes then the project should be evaluated against the criteria for ethical review (section 2.5). If outcomes are not used for research purposes, then the procedure below should be followed.

At the outset of appropriate projects/classes/experiments, it is the duty of the academic supervisor to communicate the relevant information detailed below to the participants.

i) **In any practical teaching or research schedule in which ill-health in a subject may be discovered incidentally, the following information shall be included in writing or displayed:**

Students will be asked to participate on the understanding that:

a) the procedure is explained and understood to be entirely voluntary;

b) the student has a right to decline to participate or, having accepted, to withdraw at any time;

c) declining or accepting to participate shall not affect the assessment of work in any way;

d) the student is in good health and knows of no reason why he/she should not participate;

In the event of untoward results being obtained, the following may be helpful:

ii) **Where the supervisor alone is the investigator, he/she should:**

a) advise the student about the variations between individuals for that measurement;

b) indicate that it is possible that, however unusual a result may be at first sight, there may be several well-documented anomalies;

c) avoid the concept of ‘normal/abnormal’, but rather employ the concept of ‘a range of reference values’;

d) cite, for example, the case of red hair – i.e. red hair is unusual in Caucasian races, but not unhealthy;

e) resist any attempt to interpret the results within the Faculty/Department, particularly in terms of medical significance or diagnosis;

f) advise the student to consult a medical doctor in confidence in the first instance. It will be the responsibility of the subject to take or disregard the advice.

iii) **Where a student is acting as the investigator:**

a) the procedures set out above should be explained to the student by the academic supervisor, including the requirement by any investigator to treat any results with the strictest confidence;

b) where an untoward result is obtained, the investigator should report the matter as soon as possible to his/her academic supervisor, who will then take appropriate action.

6. Guidance on the Use of Questionnaires

6.1. The use of questionnaires and testing within and outside the University.

Note

The words 'questionnaire' and 'testing' are used here on the presumption that they include any systematic technique for eliciting information by and/or from any individual student, member of staff, other member of the University or member of the general public.

When the questionnaire meets any of the criteria in section 2.5 the questionnaire along with other relevant documentation should be submitted to the relevant Ethics Committee. Other questionnaires need not, of necessity, be submitted for ethical review, provided that the following guidelines are observed:-

a) The purpose of the questionnaire or test shall be clearly defined by the tester or researcher who has a responsibility to explain to the participants as fully as possible (i.e. without prejudicing the objectives of the study) what the research is about, who is undertaking and financing it, and why it is being undertaken.

b) When the participant is a student, the questioner or tester shall inform the participant if completion of the questionnaire or attendance at a test is an obligatory part of the participant's programme, or will in any way contribute towards the participant's final assessment.

c) Notwithstanding the agreement of an individual to participate in any questionnaire, survey or testing covered by the guidelines above, he or she may, at any stage, withdraw that agreement.

d) The information from any individual questionnaire shall remain confidential, and the anonymity of respondents shall be preserved.

e) In all cases where there occurs either a deliberate or accidental breach of confidentiality, the individual conducting the survey or testing shall be held responsible.

f) Publishing or divulging information to another person, Faculty/Department or researcher from which individual identity may be deduced shall be only with the written consent of the individuals concerned immediately prior to publication.

g) Any researcher processing personal data shall be aware of and comply with the provisions of current data protection legislation. The Committee's template consent form includes a paragraph on the UK data regulation's which can be amended as required by the researcher.

h) It is permissible for a research worker, member of staff or other member of the University to display notices calling for participants to answer questionnaires or participate in any form of research, subject to the normal courtesies and rules governing the use of notice boards, pigeon-holes and circulation systems. These notices shall aim to give details about the level of commitment involved.

i) Provided that the conditions about the recruitment of participants are met, specified in section 7, a student or other member of the University shall be free to participate in any form of questionnaire, survey, research or service testing, except during hours specifically timetabled for academic purposes, when the prior consent of the member of staff concerned shall be sought by the person conducting the enquiry.

j) As a matter of courtesy, any undertaking given to participants by the investigator or tester shall be honoured, even if the information gathered may not be used subsequently. For example, if householders are told that completed questionnaires will be collected, then arrangements shall be made to do this.

7. Guidance on the Recruitment of Participants for Research

7.1. Advertising to recruit participants for research studies

Any advertising on the student campus, which involves the recruitment of participants for research studies, must state that either the study has had a review from the relevant ethics committee, or that the self-assessment SAFE form has been completed. Recruitment materials (e.g. posters) for recruiting participants into a research study must only be placed on designated noticeboards on the University campus. Advertising outside the University campus, either online or otherwise, must be done with the permission of either the relevant authority or the owner of the premises, noticeboard or website.

Students who wish to use other University of Surrey students as a data source can contact the Students Union, who can promote the survey in their weekly digital all-student newsletter. No general email call to students is allowed.

7.2. Guidance for external researchers from outside the University seeking to use University students and/or staff as participants

a) Researchers from, and research protocols generated outside the University, but wishing to use University students and/or staff as participants, must first seek an academic 'assessor' from within the University, who is independent of the sponsors. The 'assessor' shall not be liable for any issues arising from the research, but shall be responsible for ensuring that the protocol falls within the provisions of the Ethics Handbook.

b) All proposals by an external sponsor wishing to use students and/or staff as participants must be submitted to the Ethics Committee for ethical review. All such protocols shall be accompanied by a statement from the sponsors accepting full responsibility for any issues.

c) In the interests of the students concerned, the names of any students participating in projects involving medical or psychological experimentation undertaken by researchers, where relevant, from outside the University, whether those projects are externally or University-based, shall be submitted to the Student's GP (with their permission). This information will be subject to the usual requirements for the preservation of medical confidentiality.

7.3. Guidance on research using the internet or social media

Any research involving recruitment of or interaction with research participants via internet or social media, is expected to conform to the same principles of informed consent and the same values of care and respect as other forms of research. The exact form that the informed consent process takes will need to be decided on a case-by-case basis with due consideration for the potential risks of the research, the level of commitment asked of participants and the features of the online platform concerned.

Any research involving recruitment of or interaction with research participants via internet or social media that also addresses sensitive issues or involves vulnerable groups will need to take particular care that arrangements are in place to brief participants appropriately and refer them to ongoing support as necessary. Useful resources for making decisions about ethical aspects of internet research include the guidelines published by the Association of Internet Researchers (http://aoir.org/ethics/).

The University has a Social Media Policy which gives guidance on the mitigation of risks associated with the use of social media in a professional capacity.

8. Payments, Incentives and Financial Inducements

8.1. Personal payments to Investigators, Faculties/Departments and Institutions

Personal payments received by investigators, and their pecuniary relationship with any sponsoring company have ethical implications.

Details of specific payments to investigators, faculties/departments or institutions must be reported to the Ethics Committee when submitting a protocol. This information will be treated in confidence.

Investigators who receive payment as part of an annual consultancy fee must advise the Committee of this situation, but further details of such payments will not normally need to be declared.

8.2. Payments to participants and/or organisations

Payments can be made to individual participants to reasonably reimburse them for time and for direct expenses. Payments can be made to organisations to offset direct costs of providing for research to take place e.g. postal costs, room hire. However, it is unusual for any other fee to be paid and any payments of this nature should be clarified with your Faculty (if appropriate) and the Ethics Committee.

8.3. Incentives for participants in research

The use of compensation (rather than incentive) in clinical trials is well established, accepted and widespread. However, if incentives are used to recruit participants to a research study, they should not be too large an incentive or they may be viewed as undue inducement, and impair the personal judgement of the participant and potentially compromise their informed consent.

Therefore, any research in the UK which includes incentives to more than the minimum national hourly wage or to an accumulative total of £100 (whichever is higher), or any type of incentives offered outside the UK, or protocols which otherwise offer incentives which may unduly influence participants' decision to participate, must have a full ethical review from the UEC.

Incentives for participation should not form the most prominent aspect of an invitation to participate in a study.

8.4. Contract work involving financial inducements

In every instance of a contract/project involving the evaluation of intended proprietary medicines or medical appliances, using students, members of staff or others and involving financial inducements to the participants, relevant details of that contract/project shall be notified to the RIGO and shall include details of the amount of financial inducement concerned, the nature of the contract and the medicine or appliance to be evaluated. This provision includes contract work where the objectives are primarily commercial and/or the work undertaken does not constitute scientific research.

9. Guidance on Research with Potential Hazards to Health

9.1. Hazards to health which might be occasioned by clinical trials.

These are hazards to health which might be occasioned by clinical trials, e.g. all drugs trials and the administration of substances in pharmacological doses for research purposes.

a) A signed statement from all participants shall be required certifying their informed consent to take part in the trial.

b) The participant has the right to withdraw from the study at any stage and it is the responsibility of the researcher to make this understood in advance of the study.

The consent form should make it clear whether data collected up to withdrawal point can be withdrawn or not.

c) Arrangements shall be made by the investigators for all participants engaging in clinical trials to be screened to ensure suitability and safety to join the trial.

d) The administration of drugs shall be carried out under the supervision of a registered Medical Practitioner.

e) Nobody under the age of 18 shall be allowed to participate without written parental consent.

f) The Dean of Faculty/Head of Department shall have the right to object where there is substantial interference with the work of the Faculty/Department caused either directly or indirectly through loss of time and/or efficiency of the participant.

g) An information sheet clearly identifying the parties responsible for the research, shall be made available to prospective participants soon after the initial call for participants to a particular study.

h) Every instance of a protocol involving the administration of drugs to participants shall be presented to the relevant appropriate regulatory, ethics and governance bodies.

i) In cases where a protocol, necessitating the administration or trial of drugs to or on participants involves financial inducement to the subjects, details relating to the amount of financial inducement and the nature of the drug shall be notified to the relevant Ethics Committee(s) and regulatory authority/ies at the time of submission.

j) Approval for the use of new medicinal products shall be referred in the first instance to the Medicines and Healthcare Products Regulatory Agency (MHRA) and written evidence of approval shall be obtained and submitted to the relevant Ethics Committee(s) and regulatory authority/ies.

k) In addition, insurers expect drug trials to be conducted in accordance with the Association of British Pharmaceutical Industry Guidelines. This means that where the trial is sponsored by a pharmaceutical company, that company should issue the standard ABPI form of indemnity and offer no-fault compensation.

l) The appropriate regulatory, ethics and governance bodies must be informed and consulted if any significant material change is made to a protocol that has already had a favourable ethical review.

m) Any significant untoward event occurring during or as a result of a study affecting a participant shall be communicated promptly to the participant's General Practitioner/Student Medical Officer as outlined in information provided to the participant, and be reported to the appropriate regulatory, ethics and governance bodies.

9.2. Hazards to health which might be occasioned by physiological experiments and measurements involving the inducement of more than minimal stress.

These are hazards to health which might be occasioned by physiological experiments and measurements involving the inducement of more than minimal stress by isolation, fasting, sleep deprivation, noise, exercise, exposure, submersion, electronic and/or other means. In most instances, the Guidelines (ICH GCP) for clinical trials should also be used to cover hazards to health occasioned by physiological experiments and measurements, except that, additionally:

a) Every instance of a project involving physiological experiments and measurements of the type identified above shall be presented to the relevant Ethics Committee.

b) The Ethics Committee may require that such experimentation be supervised by a registered Medical Practitioner.

c) In cases where a protocol involves financial inducements to the subject, details relating to the amount of financial inducement shall be notified to the Ethics Committee at the time of submission.

10. Data Protection, Management and Dissemination

10.1. Data protection

Data protection laws apply to all personal information about living individuals held either electronically or in a manual filing system. All users of personal information within the University must follow strict rules called ‘data protection principles’ which are outlined in the University’s Data Protection Policy. The University maintains a Data Protection Notification (registration) with the Information Commissioner’s Office (ICO), the independent authority responsible for overseeing compliance with the Data Protection legislation. This outlines, in very general terms, the personal data being processed by the University. The University's register entry number is Z6346945 and may be found by searching the Information Commissioner's public register.

Students should only obtain or use personal information relating to third parties for approved research or other legitimate University-related purposes with the appropriate informed consent from the participant. The use of personal data by students should be limited to the minimum amount of data which is reasonably required to achieve the desired academic objectives. Surveys which are entirely anonymous (i.e. the researcher has no way of knowing the identity of the respondent) will not gather personal data in the sense of the Data Protection legislation, so data protection issues are not relevant.

10.2. Security sensitive material

Any research using Security Sensitive Research Material covered by the Counter-Terrorism and Security Act 2015, will need to follow guidelines on prior notification and management of data specified in the University of Surrey’s ‘Oversight of Security

Sensitive Research' document. Ethics review should still be undertaken by the relevant Ethics Committee, where necessary according to the standard review criteria specified in 2.5. Note that not all security sensitive research will qualify for ethical review.

10.3. Consent for sharing data

When sharing data in a research collaboration with people outside the University, either within the UK, or the EU or other countries such as the US, researchers must make sure that the appropriate consents are in place.

Some funders require that where research data are considered confidential or contain *special category data* (sensitive data), award holders must seek to secure consent for data sharing or alternatively anonymise the data in order to make sharing possible.

More guidance on consent for data sharing can be found from the UK Data Service.

10.4. Research data management

The University's Research Data Management Policy requires a Data Management Plan to be created for every project. The University Library and Learning Support Services provide guidance on this. Ethics Committee reviewers may raise any specific ethical concerns in relation to data management within a protocol submitted for review but will, in general, expect researchers to comply with the University's Research Data Management Policy.

10.4.1. Research data

The University considers Research Data to be any material collected, observed or created for the purpose of analysis and on which research conclusions are based, as defined by the Research Data Management Policy. Research data must be retained for the time period stated in the Research Data Management Policy. Where specific regulations on data retention apply (for example as imposed by funding bodies), data should be retained in accordance with these regulations.

10.4.2. Research project documentation

Research Project Documents are collected as part of the administration of the research project and include but are not restricted to, contact lists, consent forms, signed contracts and variations, funding bid documents, timesheets, copies of invoices, progress monitoring records, questionnaires, information packs for participants, monitoring returns, steering group minutes, feedback forms relating to research projects. Research Project Documentation must be retained for a minimum of **six** years from completion of the project or according to the specification of the funder's data retention schedule, whichever is the greater.

10.5. Research dissemination using Open Access

The University of Surrey has an open-access mandate, which requires all academic and research staff to approve or enter bibliographic information for all of their research outputs in Surrey Research Insight Publications Database. For more information see the University SRI webpages.

APPENDIX I

Constitution of the University Ethics Committee

Chair - to be appointed for a period of three years by the Senate on the nomination of the Vice-Chancellor.

Deputy Chair(s) – to be appointed for a period of up to three years through agreement of the Committee members.

Co-opted – At least three members, at least one of whom should be medically qualified, and at least one of whom should be a lay person from outside of the University.

Nominated – At least three members from each Faculty to represent the following areas of each Faculty:

- *Faculty of Arts & Social Sciences*;
- *Faculty of Engineering & Physical Sciences*;
- *Faculty of Health & Medical Sciences*;

Student Representation – At least two members.

Ex officio – Chairs of the Faculty Ethics Committees, the NASPA Committee Chair and the Director of Health and Safety.

In Attendance – Research Integrity and Governance Office (RIGO)

APPENDIX II

University of Surrey Ethics Committees Conflict of Interest and Confidentiality Statement

Conflict of Interest

This statement serves to assist members of the University of Surrey Ethics Committees in identifying whether they may have a conflict of interest in relation to an application they are asked to review and whether it would be advisable to decline reviewing this particular application.

It is vital that all reviewers are seen to be impartial at all stages of the review process. You should not take part in the review of any proposal where a conflict of interest may be experienced or perceived. All declared conflicts of interest will be recorded against applications. Members of the University of Surrey's Research Integrity and Governance Office (RIGO) will endeavour to identify conflicts of interest and will not select you as reviewer if there is a clear conflict. Not all conflicts are however obvious from the information available. **If you consider you may have or be perceived to have a conflict of interest you must contact the RIGO before proceeding with the review.** It is important that you ensure you are eligible to review the proposal before undertaking the review. A list of possible conflicts that may exclude you from assessing a proposal is included below. **This is not an exhaustive list; if you are in any doubt about whether or not you should assess a proposal, please contact the RIGO, who may refer to the Chair of the relevant ethics committee for a decision**. Lay members are under the same duty to identify and report potential conflicts of interest as members from within the University and should refer any concerns in this regard not covered by the criteria listed below to RIGO on a case-by-case basis.

Examples of Conflicts of Interest for University of Surrey Ethics Committees' members conducting reviews

A conflict of interest may occur or be perceived when you:

- Are a relative of the applicant or have another significant personal relationship with the applicant (e.g. close friendship or romantic).
- Have a significant professional relationship with the applicant (e.g. are currently the PhD supervisor or line manager for one or more applicant(s)) or had such a relationship in the past
- Are directly involved in the work that the applicant proposes to carry out and/or have assisted the applicant with their application.
- Have a vested interest in the outcome of the application, whether that be negative or positive, e.g. the current project competes for the same funding or you would benefit from the applicant's work to progress your own research.
- Have collaborated on a research project, or worked closely with the applicant in the last five years. In the interest of maintaining sufficient expertise to fulfil review adequately, simply working in the same Department or School as the applicant does not necessarily exclude you from reviewing the application, unless one or more of the other exclusions apply.
- Have been approached and agreed to be a member of a committee or group connected with the research project. If, for example you are a member of an advisory group or steering committee, you should not - if approached - also act as a reviewer for that project.
- Feel you may otherwise have a bias towards the outcome of the application.

Please note that, **the restrictions which apply to the Principal Investigator or Applicant, apply equally to any Co-Investigator(s) on an application.**

Confidentiality

It is expected that members of University of Surrey Ethics Committees will treat material submitted for review as confidential and not make use of it for any other purpose. Members must never derive academic or commercial competitive advantage from knowledge they acquire in the process of reviewing applications.